

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Smith et al. **EXAMINER:** Cris L. Rodriguez
SERIAL NO.: 10/721,526 **CONFIRMATION NO.:** 5331
FILED: November 25, 2003 **ART UNIT:** 3763
FOR: *RESETTABLE SAFETY SHIELD FOR MEDICAL NEEDLES*

CERTIFICATE OF MAILING

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PROPOSED
AMENDMENT AND RESPONSE

Sir:

In response to the Office Action dated June 10, 2005, please consider the following amendments and the remarks set forth below.

IN THE CLAIMS:

Applicants amend claims 5, 26 and 32, as follows:

1. (Original) A medical needle shield apparatus comprising:

a needle hub having an outer needle cannula extending therefrom to a distal end, an inner
needle being disposed for slidable movement with the outer needle cannula; and

at least one shield being extensible from a retracted position to an extended position to
enclose a distal end of the inner needle,

the shield including a binding member disposed within the shield and defining binding
surfaces that form an aperture configured for slidable receipt of the inner needle between the
retracted position and the extended position,

the binding member including at least one drag inducing member such that the at least
one drag inducing member engages the inner needle during slidable receipt of the inner needle to
create a drag force with the inner needle, the drag force and shield facilitating rotation of the
binding member relative to a longitudinal axis of the inner needle such that the binding surfaces
engage the inner needle to prevent slidable movement of the inner needle in the extended
position of the shield,

the binding member further including a needle communicating surface extending
therefrom such that the needle communicating surface is engageable with the inner needle to
prevent rotation of the binding member,

a retainer for releasable engagement with the needle hub, and

the binding member further including a binding member reset surface aligned with a hub
reset surface.

2. (Original) A medical needle shield apparatus as recited in claim 1, wherein the at
least one drag inducing member defines a cavity that is substantially aligned with the aperture,

the cavity being configured for slidable receipt of the needle to create the drag force with the needle.

3. (Original) A medical needle shield apparatus as recited in claim 1, wherein the binding member includes a substantially planar aperture plate that includes the binding surfaces that form the aperture.

4. (Original) A medical needle shield apparatus as recited in claim 3, wherein the at least one drag inducing member includes a pair of arms extending from the aperture plate.

5. (Currently Amended) A medical needle shield apparatus as recited in claim 4, wherein ^{said pair of arms} the arm includes a deflectable member.

6. (Original) A medical needle shield apparatus as recited in claim 1, wherein the binding member is rotatable, relative to a longitudinal axis of the inner needle, between a non-binding orientation whereby the inner needle is slidable relative to the binding member and a binding orientation whereby the binding surfaces engage the inner needle to prevent slidable movement of the inner needle in the extended position of the at least one shield.

7. (Original) A medical needle shield apparatus as recited in claim 1, wherein the shield includes a housing that defines at least one blocking member extending from an interior surface thereof, the at least one blocking member being engageable with the binding member for urging the binding member to a binding orientation.

8. (Original) A medical needle shield apparatus as recited in claim 3, wherein the shield includes a housing that defines at least one blocking member extending from an interior surface thereof, the aperture plate being axially movable for engagement with the at least one blocking member that causes rotation of the binding member to a binding orientation.

9. (Original) A medical needle shield apparatus as recited in claim 1, wherein the at least one shield is supported for relative rotational movement by at least one bearing.

10. (Original) A medical needle shield apparatus as recited in claim 1, wherein the inner needle is attached to a handle for manipulation thereof.

11. (Original) A medical needle shield apparatus as recited in claim 1, wherein the needle hub is releasably mountable with a housing of the at least one shield.

12. (Original) A medical needle shield apparatus as recited in claim 1, wherein the needle hub defines a hub slot that is configured to receive the retainer of the binding member.

13. (Original) A medical needle shield apparatus as recited in claim 1, wherein the binding member includes at least one outwardly arcuate arm that extends to the needle communicating surface.

14. (Original) A medical needle shield apparatus as recited in claim 1, further comprising a plurality of shields.

15. (Original) A medical needle shield apparatus as recited in claim 1, wherein said binding member reset surface comprises the distal facing surface of said retainer.

16. (Original) A medical needle shield apparatus as recited in claim 1, wherein said hub reset surface is configured to deflect said binding member reset surface to facilitate rotation of the binding member relative to said longitudinal axis such that said binding surface disengages the inner needle.

17. (Original) A medical needle shield according to claim 1, wherein said medical needle is adapted for bone biopsy.

18. (Original) A medical needle shield according to claim 1, wherein said medical needle is adapted for catheter introduction to a patient.

19. (Original) A medical needle shield apparatus as recited in claim 1, wherein said hub reset surface is separate from said hub and urged by a spring toward said binding member reset surface.

20. (Original) A medical needle shield apparatus of claim 19, further comprising a luer male taper configured with said hub.

21. (Original) A medical needle shield according to claim 1, wherein said medical needle operates in communication with a port access device.

22. (Original) A medical needle shield according to claim 1, further comprising a protective needle sheath member.

23. (Original) A medical needle shield apparatus comprising:

a needle hub having an outer needle cannula extending therefrom, an inner needle being disposed for slidable movement with the outer needle cannula; and

a shield being extensible from a retracted position to an extended position to enclose a distal end of the outer needle cannula,

the shield including a binding member disposed within the shield and defining binding surfaces that form an aperture configured for slidable receipt of the outer needle cannula between the retracted position and the extended position,

the binding member including at least one drag inducing member such that the at least one drag inducing member engages the outer needle cannula during slidable receipt of the outer needle cannula to create a drag force with the outer needle cannula, the drag force and shield facilitating rotation of the binding member relative to a longitudinal axis of the outer needle cannula such that the binding surfaces engage the outer needle cannula to prevent slidable movement of the outer needle cannula in the extended position of the shield, and

the binding member further including a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the outer needle cannula to prevent rotation of the binding member.

24. (Original) A medical needle shield apparatus as recited in claim 23, wherein the binding member is rotatable, relative to a longitudinal axis of the outer needle cannula, between

a non-binding orientation whereby the outer needle cannula is slidable relative to the binding member and a binding orientation whereby the binding surfaces engage the outer needle cannula to prevent slidable movement of the outer needle cannula in the extended position of the shield.

25. (Original) A medical needle shield apparatus as recited in claim 23, wherein the shield includes a housing that defines at least one blocking member extending from an interior surface thereof, the binding member including an aperture plate being axially movable for engagement with the at least one blocking member that causes rotation of the binding member to a binding orientation.

26. (Currently amended) A medical needle shield apparatus as recited in claim 23, wherein the shield includes a funnel portion adapted for use as a probe guide at a distal end thereof configured for receipt of a probe, the probe being configured for slidable movement with the outer needle cannula.

27. (Original) A medical needle shield apparatus comprising:

a needle hub having an outer needle cannula extending therefrom to a distal end, an inner needle being disposed for slidable movement with the outer needle cannula, a handle being attached to the inner needle; and

a shield being releasably mountable to the needle hub and extensible from a retracted position to an extended position to enclose a distal end of the inner needle, the handle being disposed adjacent the shield,

the shield including a binding member disposed within the shield and defining binding surfaces that form an aperture configured for slidable receipt of the inner needle between the retracted position and the extended position,

the binding member including at least one drag inducing member such that the at least one drag inducing member engages the inner needle during slidable receipt of the inner needle to create a drag force with the inner needle, the drag force and shield facilitating rotation of the binding member relative to a longitudinal axis of the inner needle such that the binding surfaces

engage the inner needle to prevent slidable movement of the inner needle in the extended position of the shield, and

the binding member further including a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the inner needle to prevent rotation of the binding member, a retainer for releasable engagement with a hub slot of the needle hub, and a binding member reset surface aligned for engagement with a hub reset surface.

28. (Original) A medical needle shield apparatus as recited in claim 27, wherein the binding member is rotatable, relative to a longitudinal axis of the inner needle, between a non-binding orientation whereby the inner needle is slidable relative to the binding member and a binding orientation whereby the binding surfaces engage the inner needle to prevent slidable movement of the inner needle in the extended position of the shield.

29. (Original) A medical needle shield apparatus as recited in claim 27, wherein the shield includes a housing that defines at least one blocking member extending from an interior surface thereof, the binding member including an aperture plate being axially movable for engagement with the at least one blocking member that causes rotation of the binding member to a binding orientation.

30. (Original) A medical needle shield apparatus as recited in claim 27, further comprising a luer slip or luer lock attachment feature.

31. (Original) A medical needle shield apparatus as recited in claim 27, further comprising a flash chamber in communication with the inner needle, the flash chamber having a fitting that facilitates connection to a medical device.

32. (Currently Amended) A medical needle shield apparatus comprising:

a needle hub having a needle cannula extending therefrom to a distal end;

at least one shield being extensible from a retracted position to an extended position to enclose a distal end of the needle cannula; and

an adjustable depth stop device for setting desired needle insertion depth, said depth stop device slidably disposed on the needle cannula and, said at least one shield being substantially disposed within said depth stop device.

33. (Original) A medical needle shield apparatus comprising:

a needle hub having an outer needle cannula extending therefrom to a distal end, an inner needle being disposed for slidable movement with the outer needle cannula; and

at least one shield being extensible from a retracted position to an extended position to enclose a distal end of the inner needle,

the needle shield further including a reset surface aligned with a hub reset surface for engagement therewith to allow reuse of the shield in a shielded configuration.

REMARKS

This application has been reviewed in light of the Office Action dated June 10, 2005. Claims 1-33 are pending in the application. Claims 5, 26 and 32 are amended in a manner that Applicants believe overcome the rejections in the Office Action. Applicants believe that the originally submitted claims are patentable over the materials relied upon by the Examiner. However, claims 26 and 32 are amended for clarification purposes only. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicants are believed to be entitled. Applicants submit that no new matter or issues are introduced by the amendments. Support for the amendment is found throughout the specification and drawings.

Initially, Applicants gratefully acknowledge the allowability of the subject matter recited in claims 1-4, 6-31, and 33. Applicants, however, respectfully submit that in view of the amendments and remarks herein, all claims presently pending in the application are allowable.

Drawings

In the Office Action, the drawings were objected to as failing to comply with 37 C.F.R. §1.83(a) because they do not show every feature of the invention specified in the claims. However, applicants respectfully submit that a plurality of shields as set forth in claim 14 is shown in FIGURES 16, 17, 18, 20, 21, 22, 23A, 25, 26, and 27. For example, see shield 137 shown in FIGURES 17, 25, 26 and 27, and stylette shield 125 shown in FIGURES 18, 20, 21, 22, 23A. Moreover, applicants respectfully submit that a probe guide as set forth in claim 26 is shown in FIGURES 17 and 27 (see portion 146).

Claim Rejections – 37 U.S.C. § 112

In the Office Action, claim 5 was rejected under 35 U.S.C. § 112, second paragraph, because there is no antecedent basis for “the arm”.

Claim 5 has been amended to depend on claim 4 to provide antecedent basis for “the arm”.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, claim 32 was rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No 5,322,517 to Sircom et al. (Sircom '517).

However, it is respectfully submitted that amended claim 32 clearly and patentably distinguish over the Sircom '517 patent.

Referring to FIGS. 1 through 4, Sircom '517 shows a guard 5 that encloses the point of a needle when it reaches the end of the needle 1 (col. 15, lines 29-33).

In contrast, amended claim 32 of the present application recites, *inter alia*, “[a] medical needle shield apparatus comprising . . . an adjustable depth stop device for setting desired needle insertion depth, said depth stop device slidably disposed on the needle cannula and said at least one shield being substantially disposed within said depth stop device.”

The Sircom '517 patent in no way discloses or suggests structure as recited in claim 32. The Sircom '517 patent does not disclose, *inter alia*, a medical needle shield apparatus comprising an adjustable depth stop device for setting desired needle insertion depth, wherein the depth stop device is slidably disposed on the needle cannula and the at least one shield is substantially disposed within the depth stop device.

Because of the above distinctions, it is respectfully submitted that claim 32 is patentable and not obvious over the Sircom '517 patent. Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that the drawings, specification, and claims 1-33, presently pending in the application are believed to be in condition for allowance. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicants' undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 19-3542. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 19-3542 therefor.

Respectfully submitted,

Dated: June __, 2005

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